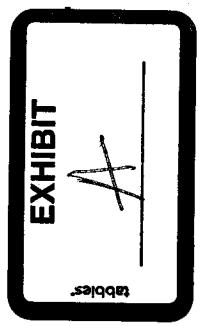
Filed Date	Category	Description	Additional Info
		Judges Notes/Comments	
8/7/2013	PET-PL	ORIGINAL PETITION/APPLICATION	PETITION
1/29/2014	ORD	ORD:OTHER ORDER	ORDER GRANTING EXTENSION OF SEAL AND TIME FOR INTERVENTION
1/29/2014	MOTION	MTN:OTHER MOTION	STATE'S MOTION TO EXTEND SEAL AND TIME TO INTERVENE (UNDER S EAL)
5/14/2014	MOTION	MTN:OTHER MOTION	STATES MOTION FOR PARTIAL UNSEALING
5/14/2014	ORD	ORD:OTHER ORDER	ORDER (FILED IN CAMERA AND UNDER SEAL PURSUANT TO TEX.HUM. RES.CODE ANN.36.102(B)
7/31/2014	MOTION	MTN:OTHER MOTION	STATE'S MOTION TO EXTEND SEAL AND TIME TO INTERVENE (UNDER S EAL)
7/31/2014	ORD	ORD:OTHER ORDER	ORDER GRANTING EXTENSION OF SEAL AND TIME FOR INTERVENTION
9/10/2014	ORD	ORD:OTHER ORDER	ORDER - Original sent to file room, picked up 9/15/14 by Melissa Reyes
9/10/2014	MOTION	MTN:OTHER MOTION	STATE OF TEXAS' MOTION FOR AN ORDER COMPELLING WITNESS TO SU BMIT TO EXAMINATION UNDER OATH (UNDER SEAL)
9/22/2014	MOTION	MTN:OTHER MOTION	STATE OF TEXAS' SUPPLEMENTAL MOTION FOR AN ORDER COMPELLING WITNESS TO SUBMIT TO EXAMINATION UNDER OATH (UNDER SEAL)
9/22/2014	NOTICE	NTC:OTHER NOTICE	STATE OF TEXAS' NOTICE OF HEARING SUPPLEMENTAL MOTION FOR AN ORDER COMPELLING WITNESS TO SUBMIT TO EXAMINATION UNDER OATH (UNDER SEAL)
9/30/2014	NOTICE	NTC:OTHER NOTICE	STATE OF TEXAS' NOTICE OF HEARING ON SUPPLEMENTAL MOTION FOR AN ORDER COMPELLING WITNESS TO SUBMIT TO EXAMINATION UNDER OATH (UNDER SEAL)
10/7/2014	NOTICE	NTC:OTHER NOTICE	STATE OF TEXAS' NOTICE OF HEARING ON SUPPLEMENTAL MOTION FOR AN ORDER COMPELLING WITNESS TO SUBMIT TO EXAMINATION UNDER OATH (UNDER SEAL)
10/31/20...	ORD	ORD:CONSOLIDATE	ORDER CONSOLIDATING ACTIONS
10/31/20...	MOTION	MTN:OTHER MOTION	PLAINTIFF'S MOTION TO CONSOLIDATE
10/31/20...	ORD	ORD:OTHER ORDER	ORDER GRANTING MOTION TO COMPEL TESTIMONY
12/30/20...	ORD	!ORD:OTHER ORDER	AGREED ORDER LIFTING AND REMOVING SEAL AND ALLOWING SERVICE OF PROCESS UPON DEFENDANTS
12/30/20...	MOTION	MTN:OTHER MOTION	STATE OF TEXAS' MOTION TO SEAL
1/8/2015	OTHER	OTHER FILING	RULE 11 AGREEMENT



CAUSE NO. D-1-GV-13-000812

STATE OF TEXAS *ex rel.* [UNDER SEAL] Plaintiffs.	§	IN THE DISTRICT COURT
v.	§	353RD JUDICIAL DISTRICT
[UNDER SEAL] Defendants.	§	

STATE OF TEXAS' MOTION TO UNSEAL

TO THE HONORABLE JUDGE OF SAID COURT:

The State of Texas ("Texas") files this Motion to Unseal, and in support thereof represents as follows:

1. This *qui tam* action was filed by Plaintiffs / Relators Layne D. Foote, Mark T. Lorden, RoseMarie De Souza, and Kenneth McDonough, M.D., pursuant to § 36.102 of the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE ANN. § 36.001, *et seq.* (the "TMFPA").

2. Having exercised its prerogative to intervene under § 36.104 of the TMFPA, Texas requests that the Court lift and remove the seal as to Plaintiffs' First Amended Petition filed December 22, 2014, and order service of process upon the following Defendants:

A. AstraZeneca L.P. and

B. AstraZeneca Pharmaceuticals, L.P.

3. Plaintiff / Relators Layne D. Foote, Mark T. Lorden, RoseMarie De Souza, and Kenneth McDonough, M.D. do not oppose this Motion.

Texas respectfully requests an order of this Court lifting and removing the seal with respect to Plaintiffs' First Amended Petition filed December 22, 2014, and ordering service of process for

Defendants. Texas requests such other and further relief, at law or in equity, to which it may be entitled.

Respectfully submitted,

GREG ABBOTT
Attorney General of Texas

DANIEL T. HODGE
First Assistant Attorney General

JOHN SCOTT
Deputy Attorney General for Civil Litigation

RAYMOND C. WINTER
Chief, Civil Medicaid Fraud Division

CYNTHIA O'KEEFFE
Deputy Chief, Civil Medicaid Fraud Division

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Civil Medicaid Fraud Division
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Phone: (512) 936-1733
Fax: (512) 463-0262

ATTORNEYS FOR THE STATE OF TEXAS

CERTIFICATE OF SERVICE

I certify a true and correct copy of the foregoing State of Texas' Motion to Unseal (filed under seal) has been sent via **electronic mail** on December 30, 2014 to:

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JUSTIN E. DUNLAP

DC BK14364 PG240

Filed in The District Court
of Travis County, Texas

DEC 30 2014

At 1:38 PM M.
Amalia Rodriguez-Mendoza, Clerk

CAUSE NO. D-1-GV-13-000812

STATE OF TEXAS *ex rel.* [UNDER SEAL] Plaintiffs,	§	IN THE DISTRICT COURT
v.	§	353RD JUDICIAL DISTRICT
[UNDER SEAL] Defendants.	§	TRAVIS COUNTY, TEXAS

AGREED ORDER LIFTING AND REMOVING SEAL AND ALLOWING SERVICE OF PROCESS UPON DEFENDANTS

CAME ON THIS DAY to be heard in the above-numbered and styled cause the unopposed *ex parte* Motion to Unseal previously filed by the State of Texas. The Court, having considered said Motion finds it to be well taken and rules that it should be GRANTED in all respects. It is therefore:

ORDERED that as of December 30, 2014, the seal in this *qui tam* matter should be and hereby is lifted and removed with respect to the Plaintiffs' First Amended Petition, and it is further:

ORDERED that service of process should be and hereby is permitted to be prepared and served upon all Defendants, requiring them to answer herein.

SIGNED this 30th day of December, 2014.

JUDGE PRESIDING

ATTORNEY GENERAL OF TEXAS

January 5, 2015

John C. Dodds
Morgan Lewis
1701 Market Street
Philadelphia, PA 19103-2921
jdodds@morganlewis.com

Via regular mail and electronic mail

Re: *State of Texas, ex rel. Layne D. Foote, Mark T. Lorden, Rosemarie DeSouza, and Kenneth McDonough, M.D. v.Astrazeneca, L.P., and Astrazeneca Pharmaceuticals, L.P.* District Court, 353rd Judicial District, Travis County, Texas, Cause No. D-1-GV-13-000812; RULE 11 AGREEMENT

Dear Jack,

This letter is to memorialize our agreement regarding service of process upon the Defendants in the above-referenced matter, as well as other related items.

You have told me that you are authorized to accept service of process on behalf of AstraZeneca, LP ("AZLP") and AstraZeneca Pharmaceuticals, L.P. ("AZPLP"). With regard to AstraZeneca PLC ("PLC") and AstraZeneca Biopharmaceuticals, Inc. ("AZB"), we agree that Plaintiffs First Amended Petition in the above-referenced cause of action will not name PLC or AZB. As part of this agreement, you represent and affirm, by your signature below, that you have the authority and legal power to enter into this agreement on behalf of AZLP, AZPLP, PLC and AZB.

It is agreed that you will accept service of the First Amended Petition in the above-referenced cause of action on behalf of AZLP and AZPLP, and waive formal service of the same. Your acceptance of service for AZLP and AZPLP is without waiver of any defense. It is agreed that the service date for the First Amended Petition will be the date on which you receive an electronic copy of the First Amended Petition via e-mail from the Office of the Attorney General (the "Service Date"). Any applicable state or federal deadlines, including but not limited to responsive pleading and removal deadlines, will begin to run on the Service Date.

You further represent and affirm that in the event Plaintiffs attain judgment against AZLP and/or AZPLP in the above-referenced matter: AZLP and/or AZPLP will not avoid, or attempt to avoid, partial or total payment or satisfaction by contending that PLC's or AZB's status as a non-defendant prevents AZLP or AZPLP from satisfying the judgment; or that AZLP or AZPLP cannot satisfy any part of said judgment without PLC's or AZB's consent; or that some or all of the funds necessary to satisfy such judgment must be obtained from PLC or AZB. The defendants assert that AZLP, AZPLP, PLC and AZB are separate corporate entities and nothing contained herein shall impair or impact their right to assert such.

You further represent and affirm that to the extent that discovery in the above-referenced case, including without limitation discovery adduced from AZLP or AZPLP, suggests some relevant and non de minimus involvement by PLC or AZB in the issues implicated in this matter, PLC and AZB agree that any discovery requests and/or subpoena or deposition notices Plaintiffs may direct to PLC or AZB may be served through then-counsel for AZLP or AZPLP, as if PLC and/or AZB were named parties in the above-referenced matter, without the need to serve any such requests through any other method of personal service, and without the need to comply with Texas Rules of Civil Procedure 205 or 191.4(b) concerning discovery from non-parties. In such event, Plaintiffs agree that PLC and AZB retain and reserve all other rights regarding objections and defenses to such requests, notices or subpoenas.

Additionally, Plaintiffs agree that AZLP and AZPLP's deadline to file a state court answer or other first responsive pleading in state court is extended to 30 days after service of the First Amended Petition.

If AZLP and AZPLP remove the case to federal court and a motion to remand is filed by Plaintiffs, it is agreed that AZLP and AZPLP's deadline to answer or otherwise respond to the First Amended Petition in federal court will be extended for 45 days after the motion to remand is denied. If no motion to remand is filed, it is agreed that AZLP and AZPLP will have 60 days from the date of removal to answer or otherwise respond to the First Amended Petition. After removal, we agree to file a joint Agreed Order in federal court detailing this extension.

If the case is remanded, then we agree that AZLP and AZPLP will have 45 days from the date of the remand order to answer or otherwise respond to the First Amended Petition in state court.

The undersigned further agree that other than to enforce the terms of this agreement, the parties shall use nothing in this agreement in any way in the above-referenced matter. This agreement shall not operate as an admission or indication of any element or basis of any claim against any party nor will this agreement operate as an admission. Neither this agreement nor any action taken pursuant to this agreement shall be offered or received in evidence in any action or proceeding as an admission of liability by any party, wrongdoing by any party, suggestion that a claim lacks merit, or any element or basis of any claim against any party.

If this letter correctly outlines our agreement and your clients are agreeable to these terms, please sign below and return this letter to me.

Sincerely,

Date: 1/5/15

Eugenia La Fontaine Krieg
Assistant Attorney General
Office of the Attorney General
Civil Medicaid Fraud Division

Attorney for the State of Texas

AGREED TO AND APPROVED:

John C. Dodds

Date: 1/8/15

John C. Dodds, Esquire
Morgan, Lewis & Bockius LLP

Attorney for AstraZeneca Pharmaceuticals, L.P. and AstraZeneca L.P.

cc: W. Scott Simmer (via electronic mail)
Alan Freeman (via electronic mail)
Teresa Cavenagh (via electronic mail)
Sarah Frazier (via electronic mail)

CAUSE NO. D-1-GV-13-000812

STATE OF TEXAS *ex rel.* [UNDER SEAL] Plaintiffs, v. [UNDER SEAL] Defendants.	§ § § § § § § § § §	IN THE DISTRICT COURT 353RD JUDICIAL DISTRICT TRAVIS COUNTY, TEXAS

PLAINTIFFS' FIRST AMENDED PETITION

DOCUMENT FILED UNDER SEAL

CAUSE NO. D-1-GV-13-000812

THE STATE OF TEXAS,	§	**IN THE DISTRICT COURT**
ex rel.	§	
LAYNE D. FOOTE, MARK T. LORDEN,	§	
ROSEMARIE DE SOUZA, and	§	
KENNETH MCDONOUGH, M.D.,	§	
Plaintiffs,	§	
	§	**TRAVIS COUNTY, TEXAS**
v.	§	
	§	
ASTRAZENECA, L.P., and	§	
ASTRAZENECA PHARMACEUTICALS,	§	
L.P.,	§	
Defendants.	§	**353RD JUDICIAL DISTRICT**

PLAINTIFFS' FIRST AMENDED PETITION

The State of Texas, by and through the Attorney General of Texas, Greg Abbott, ("Texas") and Private Person Plaintiffs/Relators Layne D. Foote, Mark T. Lorden, RoseMarie De Souza, and Kenneth McDonough, M.D. ("Relators"), Plaintiffs, bring this law enforcement action pursuant to the Texas Medicaid Fraud Prevention Act ("TMFPA"), TEX. HUM. RES. CODE ANN. Chapter 36, and common law. Plaintiffs file this First Amended Petition and respectfully show the Court as follows:

I. DISCOVERY CONTROL PLAN

1. Discovery is intended to be conducted under Level 3 of Rule 190, Texas Rules of Civil Procedure.

II. NATURE OF THE CLAIMS

2. Defendants AstraZeneca, L.P. and AstraZeneca Pharmaceuticals, L.P. defrauded the Texas Medicaid Program with false and misleading marketing of Crestor, a prescription heart drug. Defendants claimed that Crestor could (1) reverse plaque buildup in the arteries, (2) reduce the risk of death, and (3) best rival Lipitor in lowering cholesterol. Texas seeks civil damages and

penalties under the TMFPA and common law to recover Texas taxpayer dollars spent as a result of AstraZeneca's pervasive fraud.

3. Defendants directly misled governing bodies of Texas Medicaid, which allowed Crestor to obtain the benefit of placement on the Texas Medicaid Preferred Drug List ("PDL"). Placement on the PDL meant that Crestor could be dispensed to Texas Medicaid patients without restrictive "prior authorization," a difference that made doctors more willing to prescribe the drug, and thus boosted taxpayer-funded sales of Crestor by the millions. AstraZeneca also planned and implemented an unlawful promotional scheme targeting doctors and other healthcare practitioners enrolled as Texas Medicaid Providers. The scheme included promoting Crestor's efficacy for unapproved or "off-label" uses, misrepresenting the results of clinical studies, and misleadingly claiming Crestor's superior efficacy to Lipitor.

4. AstraZeneca's conduct violated federal and state law and resulted in false certifications of compliance with the law. AstraZeneca made these fraudulent misrepresentations about Crestor directly to Texas Medicaid, causing Texas Medicaid to pay millions in Crestor reimbursements starting in 2005. AstraZeneca chose increased profits over delivering truthful and complete information to Texas Medicaid. This unlawful conduct deprived both Texas Medicaid patients and doctors of the ability to make fully-informed healthcare decisions. Texas brings this suit under the TMFPA, which targets fraud at all levels of the Texas Medicaid program, and common law. *See* TEX. HUM. RES. CODE § 36.001 *et seq.*

III. PARTIES

A. Plaintiffs

5. The Plaintiffs are the State of Texas, by and through the Attorney General of Texas, Greg Abbott, ("Texas") and relators Layne D. Foote, Mark T. Lorden, RoseMarie De Souza, and Kenneth McDonough, M.D. ("Relators") (collectively, "Plaintiffs").

6. Relator Layne Foote ("Relator Foote") is a citizen of the United States and a resident of Indiana. Defendants employed Relator Foote for approximately six years, from July 2003 to October 2009, as a Pharmaceutical Sales Specialist ("PSS," or "sales representative"). AstraZeneca hired Relator Foote as a sales representative to promote Crestor (and other drugs) in the Louisville, Kentucky District. His primary assigned role was to call on physicians within his assigned district and to encourage them to prescribe Crestor for their patients. He was paid primarily according to the growth of the number of Crestor (and his other assigned drugs) prescriptions within his assigned area.

7. Relator Mark T. Lorden ("Relator Lorden") is a resident of New Hampshire. He served in the United States Marine Corps as a Commissioned Officer (First Lieutenant) and was honorably discharged. Defendants employed Relator Lorden for approximately seven years, from 2003 to February 2010, as a sales representative in the Boston, Massachusetts area. Prior to that, from 2001 to 2003, Relator Lorden was a sales representative for a company that performed contract sales work for AstraZeneca. AstraZeneca hired Relator Lorden in 2003 and assigned him to promote Crestor from its initial launch. He promoted Crestor during his entire time as an employee of AstraZeneca. Relator Lorden's duties were essentially the same as those of Relator Foote.

8. Relator RoseMarie De Souza ("Relator De Souza") is a resident of Florida. Defendants employed Relator De Souza for approximately ten years, from 2000 to February 2010 as a sales representative and, later, executive sales representative in the Orlando, Florida area. During her tenure with AstraZeneca, Relator DeSouza was promoted to Career Ladder IV (Executive PSS)—an achievement only obtained by a select few sales representatives nationwide. Relator De Souza's duties were essentially the same as those of Relators Foote and Lorden.

9. Relator Kenneth McDonough, M.D. ("Relator McDonough") is a resident of Tennessee. Defendants employed Relator McDonough for approximately thirteen years, from 1995 to 2008, as AstraZeneca's national Medical Director-Managed Care. Defendants placed Relator McDonough in charge of interacting with the medical directors of the nation's leading payers of prescription drugs, e.g., PBMs, HMOs, insurers, and self-insured companies. Relator McDonough regularly interacted with state government Medicaid officials, including Texas Medicaid officials.

10. Relators originally provided information serving as the basis for this suit to Texas. Relators filed an Original Petition under seal, pursuant to the authority granted by TEX. HUM. RES. CODE § 36.101, alleging AstraZeneca's false statements, misrepresentations, and concealment of material information in violation of the TMFPA. Relators' allegations in the Original Petition were based on their direct, independent, and personal knowledge. Relators are original sources of information underlying this First Amended Petition and provided such information to Texas in the Disclosure Statement served with Relators' Original Petition. Relators' Disclosure Statement presented substantially all material evidence and information each had in their possession at the time of the filing of the Original Petition pursuant to TEX. HUM. RES. CODE § 36.102.

B. Defendants[1]

11. Defendant ASTRAZENECA, L.P. ("AstraZeneca LP") is organized under the laws of Delaware and has its principal place of business in Delaware, at 1800 Concord Pike, Wilmington, DE 19850. AstraZeneca LP is a wholly-owned subsidiary of AstraZeneca PLC. AstraZeneca LP marketed and distributed the prescription drug Crestor in Texas. AstraZeneca LP conducts business in Texas.

12. Defendant ASTRAZENECA PHARMACEUTICALS, L.P. ("AstraZeneca Pharmaceuticals LP") is organized under the laws of Delaware and has its principal place of business in Delaware, at 1800 Concord Pike, Wilmington, DE 19850. AstraZeneca Pharmaceuticals LP is a wholly-owned subsidiary of AstraZeneca PLC. AstraZeneca Pharmaceuticals LP marketed and distributed the prescription drug Crestor in Texas. AstraZeneca Pharmaceuticals LP conducts business in Texas.

IV. JURISDICTION AND VENUE

13. Jurisdiction over the subject matter arises under the TMFPA, which provides remedies to redress Defendants' conduct in this case and authorizes this action to be brought by Texas. TEX. HUM. RES. CODE ANN. § 36.052(e). Jurisdiction is further proper because the amount sought from Defendants is in excess of the minimum jurisdictional limits of this Court.

14. Venue is proper in Travis County pursuant to the TMFPA. TEX. HUM. RES. CODE ANN. § 36.052(d). The TMFPA provides that an action filed pursuant to it "shall be brought in Travis County or in a county in which any part of the unlawful act occurred." *Id.* Venue is proper in Travis County because Plaintiffs' causes of action are based upon alleged violations of the TMFPA. Venue is also proper in Travis County because Defendants' unlawful acts occurred, in

[1] Collectively referred to throughout this Petition as "Defendants" or "AstraZeneca."

part, in Travis County. Specifically, Defendants promoted Crestor for unapproved or off-label uses in Travis County to the Texas Medicaid program, including to Texas Medicaid Providers.

V. BACKGROUND

A. Overview of the Unlawful Crestor Scheme

15. Crestor, also known as rosuvastatin calcium, is a prescription drug belonging to a group of cholesterol-lowering medicines called "statins." Statins lower cholesterol levels by blocking enzymes that are essential to cholesterol production. The use of statins has increased sharply in recent years, and they are now among the most widely prescribed medicines in the United States. In fact, approximately twenty-two percent of Americans 45 years and older take a statin drug. Statins as a group accounted for $16.9 billion in sales in the United States in 2012 alone.

16. Crestor was the seventh statin approved by the Food and Drug Administration ("FDA") in the United States, launching in 2003, over 15 years after the first statin was approved in 1987. Late to market, Crestor sales severely lagged those of its chief competitors during the first few years that it was available. For example, in 2005 Crestor had only $1.3 billion in worldwide sales while Lipitor had $12.2 billion in sales and Zocor had $4.4 billion in sales. Crestor's top three competitors so dominated the market that they controlled 91% of all statin sales according to AstraZeneca's 2005 Global Brand Strategy Plan.

17. Crestor also faced significant safety concerns following its FDA approval. Leading academic publications, advocacy groups, and even European and Canadian regulators issued articles and actions critical of Crestor's effects on the kidneys and muscles between 2003 and 2006. The FDA issued "Public Health Advisories" in 2004 and 2005 regarding specific safety issues related to "kidney failure" and "myopathy" resulting from Crestor use. FDA also sent a

Notice of Violation letter to AstraZeneca stating that AstraZeneca had misleadingly claimed that Crestor was "just as safe as" other statins.

18. AstraZeneca's corporate leadership was keenly aware that the "brand image" of Crestor was poor. Their marketing research documents indicated that doctors viewed Crestor as the least safe and least tolerable of all statins. One document concluded, "Crestor does not own an identifiable positioning other than being worst for safety." A 2004 AstraZeneca strategy document frankly acknowledged that Crestor's marketing was "not working" and that the "current course is not meeting performance targets."

19. Facing flat growth and negative publicity, AstraZeneca developed a three-part scheme to favorably distinguish Crestor from its competitors in the eyes of doctors and payers. AstraZeneca executed each component of this marketing scheme by using clinical studies, which were really vehicles for pre-determined marketing messages.

20. First, AstraZeneca falsely and misleadingly claimed to doctors and the public that Crestor was superior at lowering bad cholesterol at starting doses to its chief competitor, Lipitor. The study AstraZeneca used to support these false or misleading claims, called STELLAR, was designed to show that Crestor reduced cholesterol better than its competitors. It failed, however, to achieve statistical significance in relation to Lipitor. Despite a direct FDA warning to the contrary, AstraZeneca promoted Crestor as superior to Lipitor based on STELLAR. This misleading claim was the key to Crestor's first placement on the Texas Medicaid PDL.

21. Second, AstraZeneca made the misleading and "off-label" claim to doctors and the public that Crestor was the only statin that could stop and even reduce or "regress" the development of plaque in the arteries (atherosclerosis). The studies AstraZeneca used to support these false or misleading claims, called ASTEROID and METEOR, were designed to show that Crestor was the

best statin in treating plaque. The studies, however, were flawed support for the marketing claims that AstraZeneca made. ASTEROID, which was neither double-blinded nor placebo-controlled, was acknowledged internally as merely a "promotional" study, meaning it was unable to justify an FDA approval for a new use against atherosclerosis. Despite AstraZeneca's hopes for METEOR to justify a regression indication, that study failed to show that Crestor could reduce or regress plaque. Nevertheless, AstraZeneca continued to promote Crestor as regressing atherosclerosis and added the additional false or misleading claims that METEOR proved that Crestor could delay, halt, or stop the progression of plaque.

22. Third, AstraZeneca made misleading and "off-label" claims to doctors and the public related to outcomes, including the claim that Crestor reduced the risk of death. The studies AstraZeneca used to support those false or misleading claims, called CORONA and JUPITER, were designed to show that Crestor was the best statin at "saving lives" or had the best "outcomes." CORONA failed to produce the results it was designed to produce. JUPITER purported to show reduction of risk in heart attack and stroke, but the claims made by the company to Texas Medicaid about the study went far beyond what was actually demonstrated.

23. AstraZeneca's three-part scheme was developed at the corporate level and implemented in sales districts throughout the United States and Texas. The strategy worked both nationally and in Texas. Nationally, Crestor sales increased 62% in 2006, resulting in approximately $2 billion in sales in the United States in that year. AstraZeneca's Global PR Director stated in an email that "2006 [w]as a landmark year for CRESTOR. It was the year perception changed dramatically for us, following the ASTEROID [regression study]." In Texas, after using misleading superiority claims to persuade Texas Medicaid to add Crestor as a preferred drug in 2005, Crestor prescriptions surged uninterrupted until 2011. While Texas Medicaid had

spent less than $1 million on Crestor in 2004; it spent more than $12 million on Crestor in 2011, a 1,200% difference.

B. Defendants Specifically Targeted the Texas Medicaid Program

24. AstraZeneca's Texas Crestor sales leadership described Medicaid as a "must win." Texas Medicaid reimbursements for Crestor meant big money to AstraZeneca. Additionally, in a state as large as Texas, Medicaid's placement of Crestor in a "preferred" position relative to its competitors provided a strong signal to other state Medicaid programs, and many private insurance plans, of the wisdom of doing the same on their drug lists. Thus, AstraZeneca needed to beat Lipitor's position with Texas Medicaid in order to keep other plans from restricting Crestor's reimbursement.

25. Consequently, AstraZeneca marshaled its resources to convince Texas Medicaid's governing bodies and healthcare providers that Crestor was a unique product that was superior to Lipitor and the other statins on the market. This included (1) selecting AstraZeneca-paid doctors to testify before Texas Medicaid on Crestor's behalf under the pretense that they were speaking on their own behalf, (2) influencing the contractors who were hired to provide independent, unbiased information to Texas Medicaid, and (3) other tactics, such as letter-writing campaigns, meant to secure a "win" and keep Texas Medicaid reimbursements flowing for Crestor.

C. Crestor's FDA-Approved Indications

26. Crestor has never received FDA indications for any of the following uses:
    a. regressing or reversing atherosclerosis;
    b. delaying, stopping, or halting atherosclerosis;
    c. saving lives or reducing death or total mortality;
    d. reducing cardiovascular disease outcomes as a result of cholesterol reductions.

27. The FDA approved Crestor on August 12, 2003, to lower bad cholesterol and raise good cholesterol in patients. Specifically, the FDA approved Crestor for the following:

a. as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, non-HDL-C, and TG levels and to increase HDL-C in patients with hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Frederickson Type IIa and IIb)";

b. as an adjunct to diet for the treatment of patients with elevated serum TG levels (Frederickson Type IV); and

c. to reduce LDL-C, total-C, and ApoB in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.

28. In November 2007, the FDA approved an additional use "as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels."[2]

29. In February 2010, the FDA approved an additional use for the "primary prevention of cardiovascular disease":

> In individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, CRESTOR is indicated to:
>
> i. reduce the risk of stroke
> ii. reduce the risk of [heart attack]
> iii. reduce the risk of arterial revascularization procedures

30. Since 2003, Crestor's label has had restrictions on dosing due to the risks of muscle damage and kidney problems: "The 40-mg dose of CRESTOR should be reserved for those

[2] Crestor was approved for additional indications unrelated to this action. In October 2008, the FDA approved an additional use "as an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia)." In October 2009, the FDA approved an additional population for use as an "[a]djunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors."

patients who have not achieved goal LDL-C at 20 mg (see WARNINGS, Myopathy/Rhabdomyolysis)." These restrictions have remained essentially unchanged since 2003.

D. The FDA Regulatory System

1. The Role of the FDA in Regulating Prescription Drug Promotion

31. In the United States, the sale and promotion of prescription drugs is regulated by the FDA, pursuant to the authority granted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. Under the FDCA, new drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates efficacy and safety. Efficacy means the FDA sees "substantial evidence that the drug will have the effect it . . . is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof."[3,4] Safety means that the drug's sponsor has shown substantial evidence that the drug is safe for the conditions of use "prescribed, recommended, or suggested in the proposed labeling."[5] Importantly, FDA's determination of a drug's "safety" consists of a risk-benefit analysis that includes consideration of the severity of conditions for which the drug's approval is sought, as well as the other available treatments for such conditions.[6] Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

32. FDA approval of a drug for one use does not authorize a drug manufacturer to promote the drug for a different use without an additional FDA approval. Promotion of a drug for a non-indicated use is commonly referred to as "off-label promotion," and can result in the prescription drug product being misbranded. Even if two conditions are closely related diseases, FDA still must complete a separate review to ensure that the drug is safe and effective for the

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3 21 U.S.C. § 355 (d) (5).
4 "Substantial evidence," as used in this section, is defined at 21 U.S.C. § 355 (d) (7).
5 21 U.S.C. § 355 (d) (1).
6 *See* 21 U.S.C. § 355 (d) (7).

proposed new use. FDA's careful balancing of risk versus benefit is employed to determine whether to approve the new use.[7]

33. To determine whether a drug is safe and effective, the FDA relies on information provided by the drug's manufacturer; the FDA does not conduct clinical investigations of its own. Applications for FDA approval of pharmaceutical products (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use."[8] The FDCA requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness.[9] The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use.[10]

2. FDA Regulations Prohibit the Misbranding of Prescription Drugs

34. Under the FDCA, it is illegal to introduce into interstate commerce any drug that is misbranded.[11] The misbranding laws and regulations protect patients and consumers by ensuring that drug companies do not, for example, sell snake oil as a miracle cure for a disease unless it is found to be safe and effective for that use by the FDA. A drug is "misbranded" if the labeling is false or misleading in any particular, the labeling does not contain adequate directions for use, or the manufacturer utilizes false or misleading advertisements relating to the drug.[12] FDA

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7 *Id.*

8 21 U.S.C. § 355 (b) (1) (A).

9 *See* 21 U.S.C. § 355 (d) (7).

10 *See* 21 U.S.C. § 355 (d) (5).

11 21 U.S.C. § 331 (a).

12 21 U.S.C. § 352 (a), (f), (n). "Labeling" is a core concept of pharmaceutical regulation within the FDCA, and is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) *accompanying such article*." 21 U.S.C. § 321 (m) (emphasis added). Courts have interpreted labeling broadly to encompass printed material even when not physically attached or connected to the related pharmaceutical product. *See Kordel v. United States*, 335 U.S. 345 (1948) (explaining that if the material supplements or is otherwise textually related to a product, it is deemed to 'accompany' the product for purposes of section 201(m) of the FDCA).

regulations[13] define "adequate directions for use" to mean "directions under which the layman can use a drug safely and for the purposes for which it is intended."[14] For prescription drugs, product labeling must contain "adequate information for such use . . . under which practitioners licensed by law to administer the drug can use the drug safely *and for the purposes for which it is intended, including all conditions for which it is advertised or represented.*"[15]

35. "Intended use" is broadly defined as "the objective intent of the persons legally responsible for the labeling of drugs."[16] Intended use "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." Furthermore, "this objective intent may . . . be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." *Id.* Intended use can also be shown circumstantially.

36. FDA requires pre-approval of changes to prescription drug labels.[17] Thus, a manufacturer that creates a new "intended use" for its prescription drug product cannot amend the label without FDA approval of a drug application to include this new intended use.[18] If a drug manufacturer creates a new "intended use" for its drug and the label does not include adequate directions for that new use then the drug will necessarily be misbranded in violation of federal law.

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13 *See* 21 C.F.R. 200-369.
14 21 C.F.R. 201.5.
15 21 C.F.R. 201.100 (emphasis added).
16 21 C.F.R. 201.128
17 *See* 21 C.F.R. 314.50, 314.70. This provision does not apply to a drug company unilaterally adding newly-discovered drug safety information to the label. *Wyeth v. Levine*, 555 U.S. 555, 567 (2009).
18 FDA requires "substantial evidence" of efficacy and safety, in the form of well-controlled clinical trials, for a new intended use to be approved for a drug.

E. Texas Medicaid

1. Purpose

37. The Medical Assistance Program in Texas ("Texas Medicaid") is jointly funded by the Federal Government and Texas and was created to provide medical care and other benefits for poor and disabled individuals and families who otherwise could not afford them. In fiscal year 2011, Texas Medicaid served approximately four million individuals at a cost of $29.4 billion. Since January 2007, over 70% of Texas Medicaid enrollees have been children, while the rest are primarily elderly persons or persons with disabilities.[19]

38. Texas Medicaid includes not only Medicaid decision makers, but also Medicaid providers such as pharmacies and physicians, which enter into agreements with Texas Medicaid in order to be covered providers. Together, Texas Medicaid decision makers and providers constitute the Texas Medicaid program. The Texas Health and Human Services Commission ("HHSC") administers the Texas Medicaid program and has authority to promulgate rules and other methods of administration governing the program.

39. Prescription drugs must go through an application process to be on the list of drugs eligible to be reimbursed by Texas Medicaid, also known as the Texas Medicaid Vendor Drug Program ("VDP") formulary.[20] As noted above, the FDA approved Crestor in August 2003. Within a month of its approval by the FDA, AstraZeneca submitted four applications to the Texas Medicaid program for inclusion of Crestor on the Texas Medicaid drug formulary (one application for each of the 5mg, 10mg, 20mg, and 40mg dosages). The applications were approved on

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19 *See* http://www.hhsc.state.tx.us/research/MedicaidEnrollment/ME-Monthly.asp.

20 1 TEX. ADMIN. CODE § 354.1831 (a). The VDP formulary is also referred to as the Texas Drug Code Index or "TDCI."; 1 TEX. ADMIN. CODE § 354.1921 (b).

September 18, 2003, and from that point Crestor was available by prescription to Texas Medicaid patients.

2. AstraZeneca's interactions with and responsibilities to Texas Medicaid

40. Prescription drug makers like AstraZeneca are reimbursed for pharmaceutical products approved under the VDP program and listed on the formulary. Texas Medicaid, like all state Medicaid programs, is only authorized by federal law to reimburse for "covered outpatient drugs" and is not authorized to reimburse for drugs that are used for an indication which is not "medically accepted." An indication or use is not "medically accepted" unless it is approved by the FDA or supported by at least one of three compendia enumerated under the Federal Medicaid Act. *See* 42 U.S.C. § 1396r-8(k)(3), (6); 42 U.S.C. § 1396r-8(g)(1)(B)(i).

41. Texas Medicaid requires that drug companies provide complete, truthful, and up-to-date information as part of the VDP application process.[21] VDP applications require drug manufacturers to include the FDA approval letters, copies of the package inserts, the recommended daily dosages, and formulation of the drug. The applications state that manufacturers are responsible "for submitting notification of any changes pertaining to any of the [information required by the application] not later than the date such revisions are scheduled to occur." The VDP application also requires manufacturers to certify that all the information submitted with their application is correct and that their drug is not in violation of either state or federal law. The application further requires manufacturers, on an on-going basis, to inform HHSC in writing of any changes pertaining to their product's status within fifteen days of such changes occurring. Accordingly, AstraZeneca owed a continuing duty to Texas Medicaid to supplement information provided with their Crestor VDP applications after initial submission of those applications to VDP.

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21 *Id. See also* 1 TEX. ADMIN. CODE § 354.1923 (b).

42. Texas Medicaid also reviews classes of drugs to decide which brands to place on its Preferred Drug List ("PDL").[22] Texas Medicaid's Pharmaceutical and Therapeutics Committee ("P&T Committee") was established for the purpose of developing recommendations as to which drugs are listed on Texas Medicaid's PDL. Preferred drugs listed on the PDL are available to Texas Medicaid patients without prior authorization while non-preferred drugs require prior authorization. In practice, this means that if a physician wants to prescribe a non-preferred drug for a Texas Medicaid patient, the prescribing physician must receive approval from the Texas Medicaid program before the cost of the prescription will be covered. As one would expect, prescription drug manufacturers jockey with one another to have their drugs listed as preferred on the PDL. In making recommendations for the PDL, the P&T Committee considers the clinical efficacy, safety, and cost-effectiveness of each drug reviewed.[23]

43. As part of this PDL process, drug manufacturers present information concerning their drugs to the P&T Committee during both oral meetings and in the form of paper submissions. The P&T Committee expects—and Texas law requires—that all such information is complete and accurate. HHSC then decides which drugs are placed on the PDL primarily on the basis of the P&T Committee's recommendations. The P&T Committee cannot effectively make recommendations to manage the PDL where material information has been misrepresented and/or concealed by a drug company. Crestor was listed as a non-preferred drug on the PDL prior to the P&T Committee Meeting held on April 30, 2005. Defendants sought and achieved the placement of Crestor on the PDL following that meeting. Crestor remained in a preferred status from July 12, 2005 until July 25, 2012.

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22 1 TEX. ADMIN. CODE § 354.1924.

23 1 TEX. ADMIN. CODE § 354.1928.

VI. APPLICABLE TEXAS STATUTORY AND COMMON LAW

44. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 43 of this First Amended Petition.

45. Before September 1, 2005, a person committed an unlawful act as defined under the Texas Medicaid Fraud Prevention Act by, among other things:

a. Knowingly or intentionally making or causing to be made a false statement or misrepresentation of material fact on an application for a contract, benefit, or payment under the Medicaid Program; or that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program. Tex. Hum. Res. Code § 36.002(1)(A) & (B);

b. Knowingly or intentionally concealing or failing to disclose an event that the person knows affects the initial or continued right of the person to a benefit or payment under the Medicaid program and to permit a person to receive a benefit or payment that is not authorized, or that is greater than the benefit or payment that is authorized. Tex. Hum. Res. Code § 36.002(2);

c. Knowingly or intentionally making, or causing to be made, inducing, or seeking to induce the making of a false statement or misrepresentation of a material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program. Tex. Hum. Res. Code § 36.002(4)(B);

d. Knowingly charging, soliciting, accepting, or receiving, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program. TEX. HUM. RES. CODE § 36.002 (5).

46. Between September 1, 2005, and September 1, 2007, a person committed an unlawful act as defined under the Texas Medicaid Fraud Prevention Act by, among other things:

a. Knowingly making or causing to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. Tex. Hum. Res. Code Ann. § 36.002(1)(A) & (B).

b. Knowingly concealing or failing to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. Tex. Hum. Res. Code Ann. § 36.002(2).

c. Knowingly making, causing to be made, inducing, or seeking to induce the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program. Tex. Hum. Res. Code Ann. § 36.002(4)(B).

d. Knowingly paying, charging, soliciting, accepting, or receiving, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program. TEX. HUM. RES. CODE § 36.002 (5).

47. Since September 1, 2007, a person commits an unlawful act as defined under the Texas Medicaid Fraud Prevention Act by, among other things:

a. Knowingly making or causing to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. Tex. Hum. Res. Code § 36.002 (1).

b. Knowingly concealing or failing to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. Tex. Hum. Res. Code § 36.002 (2).

c. Knowingly making, causing to be made, inducing, or seeking to induce the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program. Tex. Hum. Res. Code § 36.002 (4) (B).

d. Knowingly paying, charging, soliciting, accepting, or receiving, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for,

in whole or in part, under the Medicaid program. Tex. Hum. Res. Code § 36.002 (5).

e. Knowingly engaging in conduct that constitutes a violation under Tex. Hum. Res. Code § 32.039(b). Tex. Hum. Res. Code § 36.002 (13).

Hereinafter, references to conduct as constituting "statutory fraud" mean that the conduct being described was done by Defendants at times when one or more of the statutory provisions set forth in this Paragraph applied, and was done in ways and through means that satisfy all the required elements of at least one applicable statutory provision.

48. Under Texas common law a person commits fraud by:

a. Making representations of material facts that are false, with knowledge that such representations are false, or by making misrepresentations recklessly, as a positive assertion, and without knowledge of their truth, with the intent that the victim act upon such representations; or by

b. Failing to disclose material facts within that person's knowledge, which he had a duty to disclose, knowing that the victim is not aware of the concealed facts and does not have an equal opportunity to discover the truth, with the intent to induce the victim to take action by failing to disclose those facts.

Hereinafter, references to "common law fraud" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in Subparagraph A or B of this Paragraph.

49. Under Texas Law, a person commits the tort of negligent misrepresentation if, in the course of his business or transactions in which he had pecuniary interests, he supplies information that is false, for the guidance of others, and he fails to exercise reasonable care or competence in obtaining or communicating the information. Hereinafter, references to "negligent misrepresentation" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph.

50. Under Texas Law, if a victim, unaware of a wrongdoer's unlawful acts, pays money that would otherwise not have been paid, such that the wrongdoer holds money that in equity and good conscience belongs to the victim, the retention of those funds by the wrongdoer would be inequitable and unjust. Hereinafter, references to "monies had and received" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph.

51. Under Texas Law, a victim can recover under promissory estoppel if a wrongdoer made a promise to the victim, the victim reasonably and substantially relied on the promise to its detriment, the wrongdoer could have foreseen the victim's reliance on the promise, and injustice can be avoided only by enforcing the wrongdoer's promise. Hereinafter, references to "promissory estoppel" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph.

VII. DEFENDANTS' UNLAWFUL ACTS

A. Defendants Promoted Crestor as Superior to Lipitor Based on Starting Doses in the STELLAR Study, Misbranding the Product in Violation of Law

1. STELLAR did not show that Crestor was more effective than Lipitor

52. The first part of AstraZeneca's scheme to increase Crestor's market share was to convince prescribers that Crestor lowered cholesterol better than other statins. To achieve this plan, AstraZeneca attempted to differentiate Crestor from the competition by claiming that its clinical trial STELLAR had demonstrated that Crestor was more effective than Lipitor in reducing cholesterol at starting doses. The FDA quickly deemed this effort to be misbranding.

53. In July 2003, "STELLAR" (**S**tatin **T**herapies for **E**levated **L**ipid **L**evels Compared **A**cross Doses of **R**osuvastatin) was published in the American Journal of Cardiology.[24] AstraZeneca based a direct-to-consumer ad campaign on STELLAR. The ads made the following comparative claims in a Dr. Seuss-like rhyme: "All cholesterol drugs simply aren't the same. When Crestor performed in a head to head test its lowering effect was clearly the best."

54. On March 8, 2005 the FDA sent AstraZeneca a Notice of Violation stating that their STELLAR ads violated the federal FDCA because they focused on irrelevant issues, such as starting doses, to compare Crestor to Lipitor. The letter stated:

> **The presentation is a misleading comparison because it relies solely on data that are not relevant to comparisons of the drugs such as most common dose or starting dose, while ignoring data that do not support the claim of superiority made in the ads**. Specifically, the comparison with Lipitor is misleading because it suggests that Crestor is superior to Lipitor when in fact none of the approved doses of Crestor was significantly superior to 80 mg of Lipitor in the STELLAR study. . . . Moreover, the 10 mg dose of Crestor was not statistically significantly more effective at LDL-C lowering than Lipitor 20 mg or 40 mg. Comparison of the most common doses or starting doses is irrelevant to the actual effectiveness of the drugs. Starting and common doses reflect a variety of influences, including doses studied in trials, commercial considerations, and toxicity concerns; however, they do not represent factors that are relevant for comparative effectiveness. **Accordingly, your suggestion that Crestor is superior to Lipitor is therefore misleading.**

(Emphasis added). The FDA requested that AstraZeneca immediately cease the dissemination of the STELLAR ads and all similar advertising. But AstraZeneca ignored this direction.

2. AstraZeneca misled Texas Medicaid to get Crestor on the PDL

55. Less than two months after AstraZeneca received the Notice of Violation from the FDA, Texas Medicaid's P&T Committee met to decide which of the statins to recommend for placement on the Texas Medicaid Preferred Drug List. Before this April 2005 meeting, Crestor

[24] *See* Peter H. Jones et al., *Comparison of the Efficacy and Safety of Rosuvastatin Versus Atorvastatin, Simvastatin, and Pravastatin Across Doses (STELLAR Trial)*, 92 Am. J. Cardiology 152 (2003).

was not on the PDL and, therefore, required prior authorization before a prescription would be reimbursed by Texas Medicaid.

56. In order to secure Crestor's preferred position on the PDL, AstraZeneca mobilized a "Texas Medicaid Team" to execute the following plan: 1) target sales calls on P&T Committee members in their private practice offices delivering STELLAR superiority messages designed to persuade these members to add Crestor to the PDL; 2) request that "physician advocates for Crestor" serving a high volume of Medicaid patients write a letter or contact P&T Committee members to urge Crestor's addition to the PDL; and 3) send AstraZeneca's Director of Strategic Development to Austin to deliver the STELLAR superiority message directly to the P&T Committee. As one AstraZeneca executive put it: "[W]e must do all that we can to ensure the placement of Crestor on the PDL. We will do everything we can to make sure that happens."

57. The Strategic Development Director's presentation to Texas Medicaid's P&T Committee emphasized AstraZeneca's Crestor superiority message based on STELLAR:

> [In STELLAR, patients] achieved their target goal on our usual 10 mg starting dose of Crestor . . . significantly more than what we saw with 10 mg of atorvastatin (Lipitor) . . . . I think we'll always look where you want to start and that's our usual starting dose. And we demonstrated that we can get more patients to goal there, you know with that start.

By focusing on effectiveness at starting doses, the presentation was not only misleading, but it was also in direct contravention of the FDA's Notice of Violation issued fewer than 60 days earlier.

58. AstraZeneca's deception worked. Following the April 2005 P&T Committee meeting, Crestor was placed on the Texas PDL as a preferred drug while Lipitor was left off of the PDL. AstraZeneca misled Texas Medicaid in the precise fashion that FDA had warned about not two months earlier. In an email sent shortly after the meeting, an AstraZeneca executive praised the Strategic Development Director's P&T efforts as being "the key to our win in Texas."

3. AstraZeneca continued to claim STELLAR-based superiority in sales efforts

59. Misleading the P&T Committee was only part of AstraZeneca's strategy to mislead Texas Medicaid. The superiority message the FDA had prohibited was repeated year after year through AstraZeneca's use of carefully crafted sales aids and strategies during calls to Texas Medicaid providers. All the while, AstraZeneca's internal documents acknowledged that the STELLAR superiority claims were misleading. Indeed, one February 2010 AstraZeneca Field Guidance document stated that "[a] claim of superior LDL-C reduction cannot be discussed . . . or linked to LDL-C data within STELLAR . . . . Making any of the connections (involving STELLAR) . . . would be considered false and misleading and off-label promotion."

60. Defendants' planning and promotion of Crestor's efficacy as superior compared to Lipitor based on STELLAR demonstrates Defendants' intent to expand the use of Crestor beyond its FDA-approved uses. By planning to promote, and then promoting, Crestor in this false or misleading manner, Defendants created a new intended use for Crestor or disseminated false or misleading advertisements for Crestor, causing the drug to be misbranded in violation of federal and Texas state law. AstraZeneca used STELLAR as part of a fraudulent scheme to mislead the Texas Medicaid program. STELLAR's misuse harmed Texas Medicaid's ability to make fully-informed and appropriate policy decisions. This ability is crucial to Texas Medicaid's mission to ensure appropriate patient care and conserve Medicaid resources.

B. Defendants Misleadingly Promoted Crestor for Use in Reducing or Regressing Plaque in the Arteries, Misbranding the Product in Violation of Law

61. The second part of AstraZeneca's scheme to increase Crestor's market share was to illegally promote Crestor as reducing or regressing atherosclerosis, an effect that, if reliably

demonstrated, would be considered a "Holy Grail" in cardiology.[25] As noted above, Crestor was initially FDA-approved only to lower bad cholesterol and raise good cholesterol. But since all statins did that, AstraZeneca recognized that Crestor's success depended on "differentiating" itself from chief rivals Lipitor and Zocor. The corporate "Crestor Leadership Team" thus planned to market Crestor for an unapproved new use—regression of atherosclerosis—which allowed it to capture even more of the Texas Medicaid market for statins. The marketing message was simple, false, and misleading: "Atherosclerosis is the leading cause of morbidity and mortality claiming more lives each year than all forms of cancer combined . . . *Crestor can slow, stop, and regress atherosclerosis*." (Emphasis added).

1. AstraZeneca's plaque "regression" claims were based on the scientifically-dubious ASTEROID "promotional" study

62. The vehicle to deliver the misleading and off-label regression message was an open-label, non-placebo-controlled, "promotional" study called "ASTEROID" (**A** Study **To** **E**valuate the Effects of **R**osuvastatin **On** **I**ntravascular **D**erived Coronary Atheroma Burden).[26] Not only did AstraZeneca fund the ASTEROID study, the company also "participated in discussions regarding study design and protocol development" and "was permitted to review the manuscript and suggest changes."[27]

63. AstraZeneca's involvement also included close ties to an author of the ASTEROID study. For example, in an email exchange with AstraZeneca public relations executives, this author of the study emphasized the importance of "staying at arm's length from the study's sponsor," while at the same time he clearly coordinated media activities and press releases in the months

[25] An internal email circulated around the AstraZeneca brand team and sales leadership stated that ASTEROID was a "landmark" study because "regression [of] plaque is considered the 'holy grail' of CV treatment."
[26] *See* Steven E. Nissen et al., *Effect of Very High-Intensity Statin Therapy on Regression of Coronary Atherosclerosis: The ASTEROID Trial*, 295 JAMA 1556 (2006).
[27] *Id.* at 1564.

leading up to ASTEROID's release. AstraZeneca produced a video of the author's important speech announcing ASTEROID, with the author's permission, which AstraZeneca then used to aid its sales force in promoting the study results. The author even sent an encouraging message about how the study results were positively affecting AstraZeneca stock prices.

64. The company's enthusiasm with ASTEROID was unfounded. In fact, the scientific weakness of the ASTEROID study is revealed by AstraZeneca's own United States Product Strategic Plan, which described ASTEROID as being merely for "promotional support." AstraZeneca understood, in other words, that the ASTEROID trial alone was not scientifically rigorous enough to support a new FDA indication for the regression of atherosclerosis.[28]

65. Unsurprisingly, when the non-placebo-controlled "promotional" ASTEROID study was published in March 2006, it purported to show a positive result for Crestor: that the drug could reverse the progression of plaque in the arteries for those patients taking a 40 mg dose. However, this result has never been duplicated in a study meeting FDA's standards for evidence needed for a new indication, despite serious attempts by the company to do so. Nevertheless, using ASTEROID, AstraZeneca sought to convince key decision-makers in Texas and beyond that Crestor had the unique capability to reverse or regress atherosclerosis. In doing so, AstraZeneca would ensure that Crestor became a blockbuster drug.

2. AstraZeneca planned to promote Crestor for use in regressing atherosclerosis, trained its sales force, and implemented that plan

66. The Crestor Leadership Team planned to use the ASTEROID study to market Crestor for the regression of atherosclerosis even though Crestor did not have an FDA indication for that use. An executive-level sales document touted Crestor as "the first statin to show regression of atherosclerosis" while stating that "[i]mmediate opportunities exist to enhance Crestor

[28] Most notably, the ASTEROID study was neither double-blinded nor did it have a placebo or active comparator.

performance" by "solidify[ing] Crestor as the leader in atherosclerosis regression."

67. The "Crestor Senior Advisory Board" determined that the Crestor marketing focus should be built around the message that Crestor "reverses coronary atherosclerosis." The list of AstraZeneca attendees at the meeting included the Vice President of Strategic Development, the Crestor Commercial Brand Leader, the Senior Therapeutic Brand Leader, and the Crestor Brand Leader. The regression messaging was so important to Crestor's success that AstraZeneca's National Sales Director was even personally evaluated in December 2006 on how well sales representatives were executing ASTEROID messaging during sales calls to doctors.

68. From the beginning of 2006, AstraZeneca's sales force was extensively trained on ASTEROID so that the regression message could be delivered effectively to physicians during sales calls in the field. Sales reps were expected to be able to discuss the specifics of ASTEROID with doctors and an ASTEROID "Reprint Worksheet" was used to the test the knowledge of the sales force.

69. AstraZeneca documents show that Texas regional sales directors and district sales managers directed their sales representatives to promote and discuss ASTEROID and regression with physicians. In fact, Texas sales managers made ASTEROID a top sales strategy in 2006 and beyond. A San Antonio-area sales manager stated that in the weeks after ASTEROID was released that Crestor was now "in re-launch mode" and that "[a]ll customers must be seen asap." Another sales manager forwarded an e-mail to his sales representatives directing that ASTEROID should be discussed on every sales call with physicians. The Texas sales director forwarded an email to the sales team stating that "[the] difference [between Crestor and Lipitor] is Crestor showed regression by ***whatever mechanism a physician wants to assume*** is the method – Lipitor did not."

(Emphasis added). To Defendants, it did not matter what was true as long as the message was regression.

70. The regression and ASTEROID messaging was also used at AstraZeneca-paid physician/speaker events. These speaker events were typically high-end complimentary lunches or dinners, at which an AstraZeneca-paid physician/speaker would promote Crestor. The ASTEROID results were a frequent topic for these events. AstraZeneca developed a special slideshow presentation for the speakers that highlighted the ASTEROID results. Sales reps would often, in their words, "plant" a question in the audience to trigger the ASTEROID discussion. Off-label marketing of ASTEROID and regression was a coordinated and widespread practice.

71. Texas sales representatives were required to enter "call notes" into a computer system after a sales call with a physician that described what was discussed during the sales call. Texas has identified thousands of Texas call notes in which sales representatives reported in their contemporaneous notes that they had engaged in the false and misleading promotions with doctors about ASTEROID and regression.

72. Defendants knowingly implemented a regression messaging scheme on a massive scale throughout the United States and in Texas despite the fact that the company's own internal documents acknowledged that "the ASTEROID study describes off-label uses of Crestor" and should not be discussed with physicians.

3. AstraZeneca directed its regression messaging to Texas Medicaid

73. In addition to the thousands of Texas call notes demonstrating the false and misleading marketing of regression to physicians during sales calls, AstraZeneca made sure that the Texas Medicaid P&T Committee heard about Crestor's purported ability to regress plaque. With the goal of ensuring Crestor remained on the Texas Medicaid PDL, AstraZeneca arranged

for doctors to appear on Crestor's behalf at the May 2006 and April 2008 P&T Committee meetings in order to deliver their ASTEROID message. In February 2006, AstraZeneca arranged the appearance of a Texas nephrologist and AstraZeneca-paid Crestor speaker at the committee meeting. What was unknown to the Committee, however, was that an AstraZeneca sales representative had "instructed [the doctor] . . . on what to say and what challenges he might face in front of the [committee]," according to an internal email.

74. The doctor did not disappoint the company. Claiming that he was representing himself, the doctor delivered the misleading and off-label message that Crestor could "reduce – atherosclerotic disease" to the P&T Committee. The sales representative who prepared the doctor for his P&T Committee testimony won a "Being the Best" award (with a cash prize) for the "instrumental" role he played in "winning the Texas Medicaid formulary bid."

75. The same misleading regression message was delivered by a cardiologist during the April 2008 P&T Committee meeting. The cardiologist, also an Astra-Zeneca-paid promotional speaker, was considered so effective at "selling Crestor" that a company list of promotional speakers provided contact information "to book" him for speaking engagements. In 2012 alone, AstraZeneca paid the cardiologist well over $100,000 in speaker fees.

76. The cardiologist claimed that he was testifying before the P&T Committee "on behalf of my patients," but in reality AstraZeneca had chosen him to speak and prepared him for his appearance. He delivered the company's false and misleading regression message to the P&T Committee: "I know there are at least a half a dozen statins . . . but I sincerely and truly believe that in certain high-risk patients, . . . [who] make up a bigger chunk of the Medicaid population, . . . truly will benefit from a statin of this unique, unique property that can reverse atherosclerosis."

Not surprisingly, following each of the meetings in which the doctors testified, the P&T Committee recommended that Crestor be placed again on Texas Medicaid's PDL.

77. Defendants' planning and promotion of Crestor for use in regressing or reversing atherosclerosis demonstrates Defendants' intent to expand the use of Crestor beyond its FDA-approved uses in managing cholesterol. By planning to promote, and then promoting, Crestor in this false or misleading manner, Defendants created a new intended use for Crestor or disseminated false or misleading advertisements for Crestor, causing the drug to be misbranded in violation of federal and Texas state law. AstraZeneca's fraudulent marketing scheme utilized ASTEROID to mislead the Texas Medicaid program. The fraudulent ASTEROID marketing prevented Texas Medicaid from making fully-informed and appropriate policy decisions, which are key to conserving Medicaid resources and ensuring appropriate patient care.

4. AstraZeneca spun the METEOR trial results to support the regression message

78. Because ASTEROID was clearly only a marketing study without a placebo control or a comparator, the company set out to conduct a more rigorous study to prove its regression hypothesis. AstraZeneca designed a study, called METEOR,[29] which was intended to be rigorous enough (unlike ASTEROID) to support getting an FDA indication that Crestor causes regression of plaque. A year after ASTEROID was released, METEOR was presented at a March 2007 cardiology conference. Because the false and misleading ASTEROID promotions had been so successful in boosting Crestor's market share, AstraZeneca's scheme was to keep up the regression momentum with METEOR. Unfortunately for AstraZeneca, METEOR concluded that "[Crestor]

[29] *See* John R. Crouse III et al., *Effect of Rosuvastatin on Progression of Carotid Intima-Media Thickness in Low-Risk Individuals with Subclinical Atherosclerosis: The METEOR Trial*, 297 JAMA 1344 (2007).

did not induce disease regression," but only slowed the rate of progression. (Emphasis added).

79. Although METEOR had not shown regression, AstraZeneca still spun METEOR to support regression promotions. The marketing message to physicians became that (1) ASTEROID had demonstrated *regression* of atherosclerosis in patients with *established* heart disease, and (2) METEOR had demonstrated the *delaying*, *stopping*, *halting*, or *slowing* of atherosclerosis in patients with *early* heart disease. This summary of the studies was false and misleading because neither study had proven that Crestor can regress, delay, stop, or halt atherosclerosis.

80. Based on METEOR, Defendants unsuccessfully attempted to get the FDA to approve an indication for delaying atherosclerosis. According to an internal FDA email, "[AstraZeneca] got a capital 'No' from the review division on this!" Additionally, according to internal AstraZeneca documents, AstraZeneca knew that *stopping* and *halting* claims were not supported by METEOR given its short two-year duration. Ultimately, in November 2007, the FDA approved Crestor only for the limited indication of *slowing* the progression of atherosclerosis (Crestor never received an indication for regressing, delaying, stopping, or halting of atherosclerosis). By then, AstraZeneca had already been misleadingly and falsely marketing Crestor for regressing, delaying, stopping, halting or slowing the progression of atherosclerosis in Texas for over eight months. Even after Crestor received the limited indication for slowing the progression, AstraZeneca continued to misleadingly and falsely promote Crestor as regressing, delaying, stopping, or halting atherosclerosis based on METEOR.

81. As with ASTEROID, AstraZeneca planned at the highest levels to promote Crestor using METEOR to spread the regression message, training its sales force for that purpose, and implementing METEOR promotions throughout the United States and Texas. Texas contemporaneous call notes reveal that sales representatives followed the company's directives to

spin METEOR as supporting the use of Crestor in regressing, delaying, stopping, or halting atherosclerosis. These sales details continued throughout the United States and in Texas both before and after the FDA, in November 2007, had refused to grant the broader indication for regressing, delaying, stopping, or halting atherosclerosis.

82. Once again, AstraZeneca targeted Texas Medicaid's P&T Committee with the same false and misleading messages about Crestor's effect on atherosclerosis. During the May 2007 P&T Committee meeting, an AstraZeneca employee misleadingly suggested that METEOR, like ASTEROID, had shown the regression of atherosclerosis:

> [I]n the METEOR study . . . [Crestor] 40mg per day ***demonstrated significant reductions in the progression of [plaque]*** . . . and based on the positive results of the Meteor study, the Asteroid study, and the Orion MRI study, AstraZeneca has filed for an atherosclerosis indication . . . .

(Emphasis added). Not only was the message off-label, the clear and misleading implication was that a regression indication based upon ASTEROID and METEOR was a likely outcome of the FDA's review, which AstraZeneca knew to be false at the time. Once again, the deception worked. The Texas P&T Committee voted to keep Crestor on the PDL.

83. Defendants' planning and promotion of Crestor for use in delaying, stopping, halting, or (before FDA approval in November 2007) slowing the progression of atherosclerosis demonstrates Defendants' intent to expand the use of Crestor beyond its FDA-approved uses in managing cholesterol. By planning to promote, and then promoting, Crestor in this false or misleading manner, Defendants created a new intended use for Crestor or disseminated false or misleading advertisements for Crestor, causing the drug to be misbranded in violation of federal and state law. AstraZeneca's fraudulent marketing scheme utilized METEOR to mislead the Texas Medicaid program such that key decision-making about appropriate expenditures and patient care were impaired.

C. Defendants Promoted Crestor for Use in Reducing the Risk of Death, Misbranding the Product in Violation of Law

84. The third part of AstraZeneca's false and misleading scheme to increase Crestor's market share throughout the United States and in Texas was to promote Crestor for reducing the risk of death. Although Crestor's false and misleading regression and superiority marketing had boosted sales from 2005 to 2007, what Crestor really needed for long-term success was an outcomes study showing that Crestor actually reduced cardiac events and deaths. Crestor competitors Lipitor and Zocor both had FDA approval for reducing the risk of actual cardiac events since 2004; Crestor did not. An April 2005 Crestor Brand Strategy Plan noted that "no outcomes data" was a "weakness" and that "lack of outcomes data has been identified as a barrier to prescribing CRESTOR." AstraZeneca was poised to jump on any good news it could about Crestor's effect on "outcomes."

1. AstraZeneca promoted the failed CORONA study as evidence of outcomes

85. The CORONA trial (**Co**ntrolled **Ro**suvastatin Multi**na**tional Study in Heart Failure) was released at a 2007 medical conference.[30] CORONA had been designed to show that Crestor would reduce the risk of heart attack and stroke in patients with heart failure. AstraZeneca used the CORONA study to convince physicians that Crestor had "outcomes" even though the study failed to show significant improvement in heart attacks and strokes and the drug did not have an FDA-approved outcomes indication.

86. As with ASTEROID and METEOR, misleading messages were planned at the top of the company and disseminated throughout the sales organization, including in Texas. In a Crestor Product Strategic Plan, AstraZeneca stated, "CORONA . . . [will] report out in late in 2007. Our

[30] John Kjekshus et al., *Rosuvastatin in Older Patients with Systolic Heart Failure*, 357 New Eng. J. Med. 2248 (2007).

other major competitors have outcomes data in their label. . . . [W]e need to be prepared [to] . . . optimize the impact." A sales document cited CORONA as a "clinical differentiating opportunit[y] in 2007." A Field Guidance document highlighted effects from CORONA that were statistically insignificant in order to support the false and misleading claim that Crestor now had positive outcomes data: "CORONA . . . showed a[] . . . reduction in . . . cardiovascular death, [heart attack] or stroke in patients receiving CRESTOR 10 mg. . . . [T]his reduction . . . was driven by decreases in stroke and [heart attack] . . . ." But that reduction was also statistically insignificant, making the claim highly misleading as well as off-label.

87. Despite knowing that CORONA had failed to show a significant benefit in preventing heart attacks and strokes, sales representatives were directed to say so anyway. One particularly enthusiastic Texas manager wrote to his sales reps: "Do you know what Pfizer did with their studies that did not meet the primary endpoints? They used, and use them to solidify clinician's confidence and comfort with Lipitor, propelling it to market leader. Let's dig deep and master the data. . . . [T]he time is now!"

88. Even though the study had not definitively shown the benefit they claimed and the FDA had not indicated Crestor for positive outcomes, the contemporaneous call notes of the company's sales representatives show that they had sold the CORONA outcomes data about reductions in heart attacks and strokes to Texas physicians. Defendants thus knowingly implemented this false and misleading CORONA promotion despite internal company acknowledgement that explicitly warned that "the results of the CORONA study are off label" and should "not be used in discussions with health care professionals."

89. Defendants' planning and promotion of Crestor for use in reducing cardiac risk based on the failed CORONA study demonstrates Defendants' intent to expand the use of Crestor beyond

its FDA-approved uses in managing cholesterol. By planning to promote, and then promoting, Crestor in this false or misleading manner, Defendants created a new intended use for Crestor or disseminated false or misleading advertisements for Crestor, causing the drug to be misbranded in violation of federal and state law. CORONA was used by AstraZeneca to mislead the Texas Medicaid program, thus preventing Texas Medicaid from making fully-informed and appropriate policy decisions to conserve Medicaid dollars and ensure appropriate patient care.

2. AstraZeneca promoted Crestor for reducing deaths and downplayed diabetes risk based on the JUPITER trial

90. The final step in the company's deception was to sell Crestor as reducing heart attacks, strokes, and death in people with normal cholesterol levels. The JUPITER trial (**J**ustification for the **U**se of Statins in Primary **P**revention: An **I**ntervention **T**rial **E**valuating **R**osuvastatin)[31] was designed to show that Crestor reduced heart attacks, strokes, and death in people with normal cholesterol levels. Months before JUPITER was published, and before the scientific results were known, AstraZeneca announced that the JUPITER trial had stopped early due to "unequivocal evidence of a reduction in cardiovascular morbidity and mortality amongst patients who received Crestor compared to placebo," according to an AstraZeneca press release from March 2008. AstraZeneca's sales force immediately began falsely and misleadingly trumpeting the news about JUPITER's supposed effect on total mortality or "saving lives," and continued to do so for months before even knowing what the JUPITER results actually showed.

91. Ultimately, the published JUPITER trial results reported only that Crestor-treated individuals had fewer cardiovascular complications like heart attack and stroke, but Crestor was ***not*** established as a cause of reduced death. Inconveniently for AstraZeneca, JUPITER also

[31] *See* Paul Ridker et al., *Rosuvastatin to Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein*, 359 New Eng. J. Med. 2195 (2008).

showed a significantly higher frequency of the development of diabetes in patients taking Crestor than those taking a placebo, particularly in women. However, undaunted by the fact that such a claim was off-label, misleading and unproven, Crestor's purported ability to "save lives" became a central selling point for the company. For example, AstraZeneca sent a Field Guidance training document to the sales force proclaiming that "The JUPITER trial is the first primary prevention statin study to reduce total mortality. . . . These dramatic results confirm [that] CRESTOR saves lives." The document also minimized Crestor's association with diabetes in JUPITER as "a small increase in physician reported diabetes." Yet, this "small increase" in the dangerous side effect of diabetes was in fact statistically significant.

92. The sales force was trained extensively on JUPITER years before Crestor ever received an outcomes indication from the FDA. Sales managers across Texas instructed their sales representatives to set up meals and meetings to "blitz" doctors with the positive JUPITER results. Thousands of Texas call notes show AstraZeneca's false and misleading JUPITER promotion from months before it was actually published until well after Crestor received a limited risk reduction indication in February 2010. The description of JUPITER in the new FDA labeling also included the association of Crestor with increased frequency of diabetes based on the JUPITER study, even though the sales force had been deliberately downplaying that statistically significant association for nearly two years.

93. Defendants knowingly implemented a false and misleading outcomes scheme in Texas despite the fact that the company's internal documents acknowledged that "the results of the JUPITER study are off label in that they discuss a use for which CRESTOR is not currently indicated. You should not discuss the results of the JUPITER trial with health care professionals." In late 2009, AstraZeneca conducted its own internal investigation, acknowledging that "serious

compliance violations" with the promotion of JUPITER had occurred, which resulted in the firing of numerous sales representatives. However, these "serious compliance violations" relating to its promotion of JUPITER were never disclosed to Texas Medicaid.

94. AstraZeneca presented false and misleading characterizations of JUPITER to the Texas Medicaid P&T Committee in order to keep Crestor on the Preferred Drug List. During the April 2008 meeting, AstraZeneca again arranged for the AstraZeneca-paid nephrologist to testify for Crestor. While claiming to be "representing myself," the nephrologist touted the early termination and positive results of JUPITER:

> [T]he recent termination of a study of highly sensitive c-reactive protein in patients who did not have atherosclerotic disease . . . with rosuvastatin (Crestor) *reduction in the all-cause mortality* . . . makes me believe that the studies would suggest that rosuvastatin (Crestor) is an important addition to the statin armamentarium.

(Emphasis added). The doctor's comments, which were off-label, misrepresented JUPITER's mortality findings and omitted any mention about the serious diabetes risk associated with Crestor use. Following the meeting, the P&T Committee recommended that Crestor remain on the PDL.

95. During the April 2009 P&T Committee meeting, AstraZeneca again misleadingly presented the off-label JUPITER study in order to keep Crestor on the PDL. AstraZeneca's employee presented a detailed explanation of JUPITER, which even specifically downplayed the significant diabetes frequency. AstraZeneca had also arranged for another widely-used AstraZeneca-paid cardiologist to testify for Crestor. Claiming that he was "representing patients of Texas and my practice," the doctor promoted Crestor for outcomes efficacy:

> [T]he data . . . is very exciting with respect to the potential for cardiovascular risk reduction with this drug. And I think not only was the efficacy striking, we also saw reductions in every parameter of cardiovascular events . . . .

Not only did the doctor misrepresent the mortality data in the JUPITER study, he also contributed to downplaying the diabetes frequency by mentioning "the equally striking thing to me in the

JUPITER trial was . . . its extreme safety." He noted the diabetes "signal" in JUPITER and then used more recent results from another trial to say that "diabetes was assessed . . . in that study, and there was no evidence of increased diabetes." Once more, the P&T Committee recommended that Crestor remain on Texas Medicaid's PDL.

96. In addition to misleadingly promoting JUPITER to the P&T Committee in 2008 and 2009, AstraZeneca also similarly promoted JUPITER to Texas Medicaid contractor Provider Synergies, a company that prepared information for the Committee to aid it in Preferred Drug List decisions. AstraZeneca worked behind the scenes to influence Provider Synergies' work product to include points favorable to Crestor, notably JUPITER, unbeknownst to P&T members.

97. Defendants' planning and promotion of Crestor for use in saving lives, reducing total mortality, and (before FDA approval in February 2010) reducing heart attacks and strokes based on the JUPITER study demonstrates Defendants' intent to expand the use of Crestor beyond its FDA-approved uses. By planning to promote, and then promoting, Crestor in this false or misleading manner, and without the fair balance of the JUPITER diabetes results, Defendants created a new intended use for Crestor or disseminated false or misleading advertisements for Crestor, causing the drug to be misbranded in violation of federal and state law. AstraZeneca's fraudulent marketing scheme utilized JUPITER to mislead the Texas Medicaid program. The scheme undermined Texas Medicaid's ability to make fully-informed and appropriate policy decisions to conserve Medicaid dollars and ensure appropriate patient care.

D. Summary of Defendants' Unlawful Scheme

98. One final example encapsulates the misleading and off-label marketing allegations in this action. It is a 2008 e-mail from a Texas district sales manager who had been awarded the prestigious Circle of Excellence Award from AstraZeneca and had been so praised for his sales results that he was asked to visit districts around Texas and the United States to share his methods.

The e-mail was sent to his sales representatives with the subject line "MUST READ, AND LIVE BY" and included the "8 MUST items to be communicated for Crestor." Here is the list:

1. Regression in the coronary
2. Regression in the common carotid
3. Overall halting of the progression – Meteor
4. They equal Athero indication – rock solid, FDA approved
5. Death, stroke, [heart attack] . . . in the toughest to treat patients
6. Robust and literally unchallenged data against the competitors, 19-0
7. DR, you should be thinking now why you don't [prescribe] Crestor for every/most patient . . . . Corona – Crestor significantly better than placebo . . . . *It's not their fault if they don't know all the data! That's your job!*
8. $$$$$ Crestor is Less than $1 a day, electronic coupon

From this e-mail the depth of AstraZeneca's fraudulent intent is clear. The sales manager urges the promotion of Crestor for superiority (STELLAR), regression (ASTEROID), "halting of the progression" of atherosclerosis (METEOR), and death, stroke, and heart attack (JUPITER and CORONA), all of which were misleading and off-label. AstraZeneca used these studies to mislead the Texas Medicaid program, derailing Texas Medicaid's ability to make crucial policy decisions with full information, and harming the ability of Texas Medicaid to care for patients appropriately and to conserve patient resources.

VIII. CAUSES OF ACTION

A. Texas Medicaid Fraud Prevention Act[32]

1. Unlawful Acts

99. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 98 of this First Amended Petition.

[32] In September 2005 and September 2007, applicable provisions of the TMFPA were amended as set forth above. Plaintiffs are seeking the appropriate remedies for Defendants' unlawful acts (which include Defendants' conduct both prior to and after September 2005 and September 2007 for purposes of this lawsuit) as defined in the TMFPA at the time such unlawful acts were committed.

100. Defendants knowingly made or caused to be made false statements or misrepresentations of material facts to Texas Medicaid in applying for Crestor's inclusion on the Texas Medicaid Vendor Drug Program ("VDP") formulary and during the Preferred Drug List ("PDL") process. Furthermore, Defendants' false statements and/or misrepresentations permitted Defendants to receive benefits under the Medicaid program that were not authorized or that were greater than the benefits authorized, including, but not limited to, inclusion on the VDP formulary and unrestricted reimbursement of Crestor that came with inclusion on the PDL, in violation of TMFPA § 36.002 (1). Tex. Hum. Res. Code § 36.002 (1).

101. Defendants knowingly concealed or failed to disclose events or information from Texas Medicaid in conjunction with the VDP and PDL processes. This misconduct permitted Defendants to receive benefits under the Medicaid program, including, but not limited to, unrestricted reimbursement of Crestor, that was not authorized or that was greater than the benefits authorized, in violation of TMFPA § 36.002 (2). Tex. Hum. Res. Code § 36.002 (2).

102. Defendants knowingly or intentionally made, or caused to be made, induced, or sought to induce the making of false statements or misrepresentations of material facts concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program in violation of TMFPA § 36.002 (4). Tex. Hum. Res. Code § 36.002 (4) (B).

103. Defendants knowingly engaged in conduct that constituted a violation under TEX. HUM. RES. CODE § 32.039 (b). *See* TEX. HUM. RES. CODE § 36.002 (5), (13). Defendants offered or paid, directly or indirectly, overtly or covertly, remuneration, including kickbacks, bribes, or rebates, in cash or in kind to induce a person to purchase, lease, or order, or to arrange for or to recommend the purchase, lease, or order of, any good, facility, service, or item for which

payment may be made, in whole or in part, under the medical assistance program. Defendants also provided or offered an inducement to a person, including a recipient, provider, or public servant, for the purpose of influencing a decision regarding: the use of goods or services provided under the medical assistance program, or the inclusion or exclusion of goods or services available under the medical assistance program. See TEX. HUM. RES. CODE § 32.039 (b).

104. As a result of Defendants' conduct, the Texas Medicaid Program was prevented from making fully-informed and appropriate policy decisions, and from fully utilizing the tools and safeguards available to the Program, including the Texas Medicaid VDP Formulary and PDL processes, to appropriately manage the reimbursement of Crestor prescriptions. Defendants' illegal conduct, therefore, resulted in millions of dollars in excessive reimbursements for Crestor by Texas. Defendants' conduct additionally resulted in Defendants receiving the benefit of having Crestor listed and maintained on the PDL and on the Texas Medicaid VDP formulary during periods when Crestor was in violation of federal and state law.

2. Civil remedies under the Texas Medicaid Fraud Prevention Act

105. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 104 of this First Amended Petition.

106. Under the TMFPA, each Defendant is liable to the State of Texas for the amount of any payments or the value of any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of its unlawful acts; two times the amount of those payments or the value of the benefit; pre-judgment interest on the amount of those payments or the value of the benefit; and a civil penalty for each unlawful act committed, in addition to the fees, expenses, and costs of the Attorney General and the Relators in investigating and obtaining civil remedies in this matter. Tex. Hum. Res. Code §§ 36.052, 36.007, 36.110 (c).

107. Plaintiffs invoke in the broadest sense all relief possible at law or in equity under Tex. Hum. Res. Code § 36.052, whether specified in this pleading or not.

108. The amounts sought from each Defendant are in excess of the minimum jurisdictional limits of this Court. The amounts sought from each Defendant are in excess of $1,000,000.

109. The TMFPA is a statute of absolute liability. There are no statutory, equitable, or common law defenses for any violation of its provisions. Further, Texas jurisprudence provides that the defenses of estoppel, laches, and limitations are not available against the State of Texas as a Sovereign. *State v. Durham*, 860 S.W.2d 63, 67 (Tex. 1993).

110. Under the TMFPA, Defendants are liable to Texas for a civil penalty for each unlawful act committed by Defendants without regard to whether that violation resulted in harm. Tex. Hum. Res. Code § 36.052.

111. The inevitable byproduct of Defendants deluging the Texas cardiology, primary care, and other medical specialty communities with their false and misleading promotional messages regarding the safety, efficacy, and appropriate use of Crestor was that Defendants' false and misleading messages were disseminated repeatedly to thousands of Texas Medicaid providers and decision makers. Each time that Defendants knowingly made, caused to be made, induced, or sought to induce the making of such false and misleading statements to a Texas Medicaid provider or decision maker concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid Program, Defendants committed an unlawful act under the TMFPA. See Tex. Hum. Res. Code § 36.002 (4) (B).

112. Defendants also knowingly made, caused to be made, induced, or sought to induce the making of false and misleading statements in violation of the TMFPA to Texas Medicaid providers and decision makers through journal publications, promotional materials, advisory

boards, continuing medical education ("CME"), company-sponsored speeches, sales calls, and other means.

113. Texas, therefore, seeks civil penalties under the TMFPA for each of Defendants' unlawful acts under the TMFPA. Plaintiffs will seek an amount as civil penalties that will be justified and appropriate under the facts and the law.

B. Common Law Fraud

114. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 113 of this First Amended Petition.

115. Defendants made representations of material facts, including, but not limited to, the certifications on the VDP applications, to Texas that were false concerning the safety, efficacy, and appropriate use of Crestor. Defendants knew such representations were false and/or made the representations recklessly, as a positive assertion, and without knowledge of their truth with the intent that Texas act upon such representations. Texas justifiably relied upon such representations, which caused injury and damages to Texas.

116. Defendants also engaged in common law fraud by nondisclosure by failing to disclose material facts within their knowledge, which they had a duty to disclose, knowing that Texas Medicaid decision makers were not aware of the concealed facts and did not have an equal opportunity to discover the truth. Defendants intended to induce Texas Medicaid decision makers to take action by failing to disclose those facts. Texas has suffered injury as the result of acting without the knowledge of the undisclosed facts.

117. As a result of Defendants' conduct, Texas suffered harm and is entitled to recovery under common law fraud, including actual damages and prejudgment interest. Texas invokes in the broadest sense all relief possible at common law, whether specified in this pleading or not.

C. Negligent Misrepresentation

118. Texas re-alleges and reincorporates by reference as set forth herein the allegations contained in Paragraphs 1 through 117 of this First Amended Petition.

119. Defendants made misrepresentations to Texas, including, but not limited to, the false certifications on the VDP applications, by and through its Texas Medicaid decision makers and other officers and employees, in the course of the Defendants' business or transactions in which Defendants had pecuniary interests.

120. Defendants supplied information that was false for the guidance of others, and failed to exercise reasonable care or competence in obtaining or communicating the information.

121. Texas, by and through its Medicaid decision makers, officers and employees, justifiably relied on the misrepresentations.

122. Defendants' negligent misrepresentations proximately caused Texas' injuries, including pecuniary loss.

D. Monies Had and Received

123. Texas re-alleges and reincorporates by reference as set forth herein the allegations contained in Paragraphs 1 through 122 of this First Amended Petition.

124. Texas, unaware of Defendants' wrongdoing and unlawful acts, paid excessive Medicaid reimbursements that would otherwise not have been allowed.

125. Defendants hold money that in equity and good conscience belongs to Texas, and retention of those funds by any of Defendants would be inequitable and unjust in this case.

126. Defendants should be required to disgorge to Texas the revenue wrongfully and unlawfully obtained from Crestor sales ultimately reimbursed under the Texas Medicaid program.

127. Texas demands that judgment be entered against Defendants in an undetermined amount for unjust enrichment, restitution of monies gained by the Defendants, interest and costs of suit, including attorney's fees and all such other relief at law and equity to which Texas is entitled.

128. By reason of the overpayments described above, Texas is entitled to damages in an amount to be determined at trial exclusive of interest and costs.

E. Promissory Estoppel

129. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 128 of this First Amended Petition.

130. Defendants entered into a contractual promise with Texas during the VDP application process. During this process, Defendants certified Crestor's compliance with federal and state laws. Defendants additionally agreed to update Texas as to any changes, inter alia, in product status. As a result of this promise, Defendants' product Crestor was added to, and/or maintained on, the VDP formulary.

131. Texas, through VDP, reasonably and substantially relied on Defendants' promise to its detriment.

132. Defendants could have foreseen Texas' reliance on the promise, since Texas state law requires the submission of truthful information during the VDP application process.

133. Injustice can be avoided only by enforcing the Defendants' promise to comply with federal and state laws.

134. By reason of Texas' reliance on Defendants' promise, described above, Texas is entitled to damages in an amount to be determined at trial.

IX. REMEDIES FOR COMMON LAW CAUSES OF ACTION

135. As a result of Defendants' conduct, to wit: common law fraud, negligent misrepresentation, wrongfully receiving and retaining funds rightfully belonging to Texas, and promissory estoppel, Plaintiffs suffered harm as a proximate result of that conduct, and are entitled to recovery including actual damages, prejudgment interest, post-judgment interest, disgorgement, restitution for the value of all payments that Texas has made for Crestor prescriptions reimbursed under the Texas Medicaid program, and other legal and equitable relief as the Court may determine appropriate. Texas invokes in the broadest sense all relief possible at common law, whether specified in this pleading or not.

X. JURY DEMAND

136. Plaintiffs respectfully request a trial by jury on all claims pursuant to Texas Rule of Civil Procedure 216.

XI. PRAYER

137. Plaintiffs respectfully ask that judgment be entered upon trial of this case in favor of Texas and the Relators against Defendants to the maximum extent allowed by law.

138. Plaintiffs seek monetary relief in excess of $1,000,000.

139. Texas asks that it recover from Defendants under all applicable Texas common law principles:

a. its reasonable damages as they may appear at trial;

b. punitive or exemplary damages;

c. forfeiture and disgorgement of Defendants' revenues from Crestor sales in Texas in connection with Crestor use in the Texas Medicaid population;

d. restitution, under the principle of unjust enrichment, of all proceeds improperly gained by Defendants as a result of Defendants' wrongful acts, via the imposition of a constructive trust on Defendants' revenue from Crestor sales in Texas in connection with Crestor use in the Texas Medicaid population;

e. prejudgment interest and interest on the judgment; and

f. such other and further relief to which it may show itself entitled, either at law or in equity, exclusive of interest and costs.

140. Texas respectfully asks that it recover from Defendants under the TMFPA:

a. the amount of any payments or the value of any monetary or in-kind benefits provided under the Texas Medicaid program, directly or indirectly, as a result of Defendants' unlawful acts;

b. two times the amount of any payments or the value of any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of Defendants' unlawful acts;

c. civil penalties in an amount not less than $1,000 or more than $10,000 for each unlawful act committed by Defendants before May 4, 2007; in an amount not less than $5,000 or more than $10,000 for each unlawful act committed by Defendants on or after May 4, 2007 and prior to September 1, 2011; and in an amount not less than $5,500 or more than $11,000 for each unlawful act committed by Defendants on or after September 1, 2011.

d. prejudgment interest;

e. expenses, costs, and attorneys' fees; and

f. post-judgment interest at the legal rate.

141. Relators respectfully ask that they each be awarded:

a. expenses, costs and attorneys' fees;

b. Relators' shares as provided by the TMFPA; and

142. Plaintiffs, Texas and Relators, further respectfully request such other and further relief to which any party may show themselves entitled, either at law or in equity.

Respectfully submitted,

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